Project V – A randomized controlled prospective study of the next-generation probiotic, *Veillonella atypica* FB0054, vs placebo in healthy adults

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Participating Sites:	FitBiomics, Single Site Study

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Table of Acronyms

(in alphabetical order)

Acronym	Definition
AE	Adverse Event
BMI	Body Mass Index
CFR	Code of Federal Regulations
Chloe	Consumer Health Learning and Organizing Ecosystem
FDA	Food and Drug Administration
GCP	Good Clinical Practice
GSE	General Self Efficacy (a questionnaire)
HIPAA	Health Insurance Portability and Accountability Act
ICH	International Council for Harmonization
IRB	Institutional Review Board
I/E	Inclusion / Exclusion (criteria)
MFI	Multi-dimensional Fatigue Inventory (a questionnaire)
NIH	National Institute of Health
PI	Principal Investigator
QC	Quality Control
SAE	Serious Adverse Event
US	United States

Study Synopsis

In this study, we are assessing the ability of Veillonella (*Veillonella atypica* FB0054) to decrease fatigue and increase energy in a heterogeneous cohort of healthy adults compared to placebo. Study subjects will fill out a baseline health and habit survey followed by daily and weekly surveys over a two week baseline period to understand their baseline habits, fatigue, and energy levels. After this, subjects will take one daily capsule orally of one of two doses of Veillonella or placebo for four weeks, while again filling out both daily and weekly surveys. Finally, there will be a two week washout period with no supplementation but only daily and weekly surveys. At the end of the study, there will be a final experience survey.

Background and Rationale

Veillonella is a novel probiotic that can metabolize lactic acid into propionate, which is an energy source for the body [1, 2]. In previous research, we have shown that Veillonella can improve endurance compared to placebo. In mouse studies, those mice who supplemented with *V. atypica* ran 13% longer in a run-to-exhaustion test than those mice who were given placebo [1]. Furthermore, in a randomized controlled crossover pilot study, we could show that Veillonella prevented 78.7% of the performance decline observed in the placebo group in a run-to-exhaustion model [3]. We have also conducted experiments that have resulted in this product being deemed Generally Regarded As Safe (GRAS) [4].

Therefore, we believe the Veillonella is safe and likely to provide significant benefits in terms of improved endurance, increased energy, and decreased fatigue. This research study is designed to test that hypothesis. FitBiomics is sponsoring this study to confirm these effects in a broader population. FitBiomics is the first company to develop this type of bacteria as a probiotic, and this will be the largest study testing the safety and efficacy of this probiotic.

Objectives

The purpose of this research study is to:

- Test the safety and effectiveness of the study drug, Veillonella (*Veillonella atypica* FB0054), a next-generation probiotic strain.
- Identify the types of benefits observed in a broad population

Study Supplement

The study supplement here includes one of two doses of Veillonella or placebo. Veillonella contains *Veillonella atypica* FB0054 as the active ingredient with microcrystalline cellulose and hypromellose as excipients. The two doses are 15 billion cfu (high dose) and 7.5 billion cfu (low dose). Placebo capsules contain microcrystalline cellulose and hypromellose. Both Veillonella and placebo are encapsulated in acid-resistant capsules to improve delivery to the large intestine, which participants will take orally at home on a daily basis for four weeks.

Subject Selection

Participants in this study will be healthy adults interested in using Veillonella to reduce fatigue and increase energy. Subjects will be excluded from the study if they have conditions, diseases, or medications that could result in increased likelihood of AEs related to Veillonella use.

Inclusion Criteria

- Male or female adults aged 18 – 65 years.
- Willing and able to provide written informed consent.
- Ability of the participant to comprehend the full nature and purpose of the study including possible risks and side effects.
- Agreement to comply with the protocol and study restrictions.
- Fluent in written and spoken English.
- In good general health as judged by the Investigator based on medical history.
- Willing to maintain daily exercise and diet habits throughout the 8 week study without making major lifestyle changes.
- Ability to use a personal smartphone device and download the Chloe app by People Science

Exclusion Criteria

- Currently pregnant, planning to become pregnant, or lactating during the next 12 weeks
- Have a significant acute or chronic coexisting illness, disorder, or condition that contraindicates, in the Principal Investigator's judgment, entry to the study.
- Currently taking immunosuppressive medications.
- Is considered immunosuppressed for any reason.
- Currently taking medications that could impair the integrity of the gut epithelia
- Has symptoms or an illness, disorder, or cognition that impairs the integrity of the gut epithelia.
- Current antibiotic use or planned oral antibiotic use over the course of the study.
- Investigator believes that the participant may be uncooperative and/or noncompliant and should therefore not participate in the study.

Research equity

This research has no direct exclusions related to gender. There are also no direct exclusions related to race or ethnicity.

Vulnerable Populations

Vulnerable populations are not specifically targeted in this research. Racial and ethnic minorities will be included in the participants but are not specifically targeted for inclusion.

Study Procedures

See Figure 1 for details of study procedures.

Recruitment

Participants will be recruited to the study via email and social media. Interested participants will sign up though the online study landing page. Participants will be chosen from the pool of signups based on the

inclusion and exclusion criteria above. There is no maximum number of participants. All those eligible will be invited to participate. However, we estimate up to 1,000 participants will be invited to participate in the study.

Details Study Procedures

Once participants are invited to the study, they will be sent an email with a link to the Chloe application, which they will download to their mobile device. Chloe will lead them through a detailed description of the study and the informed consent process. At this point, they will also consent to sharing their fitness tracker data, as an option, if they have one. The fitness tracker data will be used to answer sleep questions and other fitness tracker data will be stored for analysis by the FitBiomics team. Once informed consent is obtained, participants will fill out a baseline health and lifestyle survey, where they will also share their mailing address. Once this survey is completed, the participant will be randomized to a high dose Veillonella (15 billion cfu), low dose Veillonella (7.5 billion cfu), or placebo in a 4:4:2 ratio respectively. These capsules will be mailed to the participant during the 2 week baseline period.

Completion of the initial baseline health and habit survey initiates the 2 week baseline period. During this period, participants will fill out daily surveys on sleep, energy, and bowel movements and weekly surveys on other benefits and adverse events (AEs) they have noticed (more details on all surveys can be found in Tables 1 and 2). On the final day of the two week baseline, they will also fill out the Multidimensional Fatigue Inventory (MFI) and General Self-Efficacy (GSE) questionnaires. At this point, participants will begin supplementation. Participants will supplement with one capsule daily for 4 weeks. During the supplementation phase, participants will fill out the same daily and weekly surveys. On the final day of the supplementation period, participants will also fill out the Multidimensional Fatigue Inventory and General Self-Efficacy questionnaires. After supplementation, there will be a two week washout period to monitor patients and to understand the lasting effect of any benefits they experienced. During the washout period, participants will again fill out the same daily and weekly surveys. On the final day of the washout period, there will be two additional surveys: one with some additional questions on changes observed throughout the study and one of open ended questions on the whole study experience.

Figure 1. Study Procedures

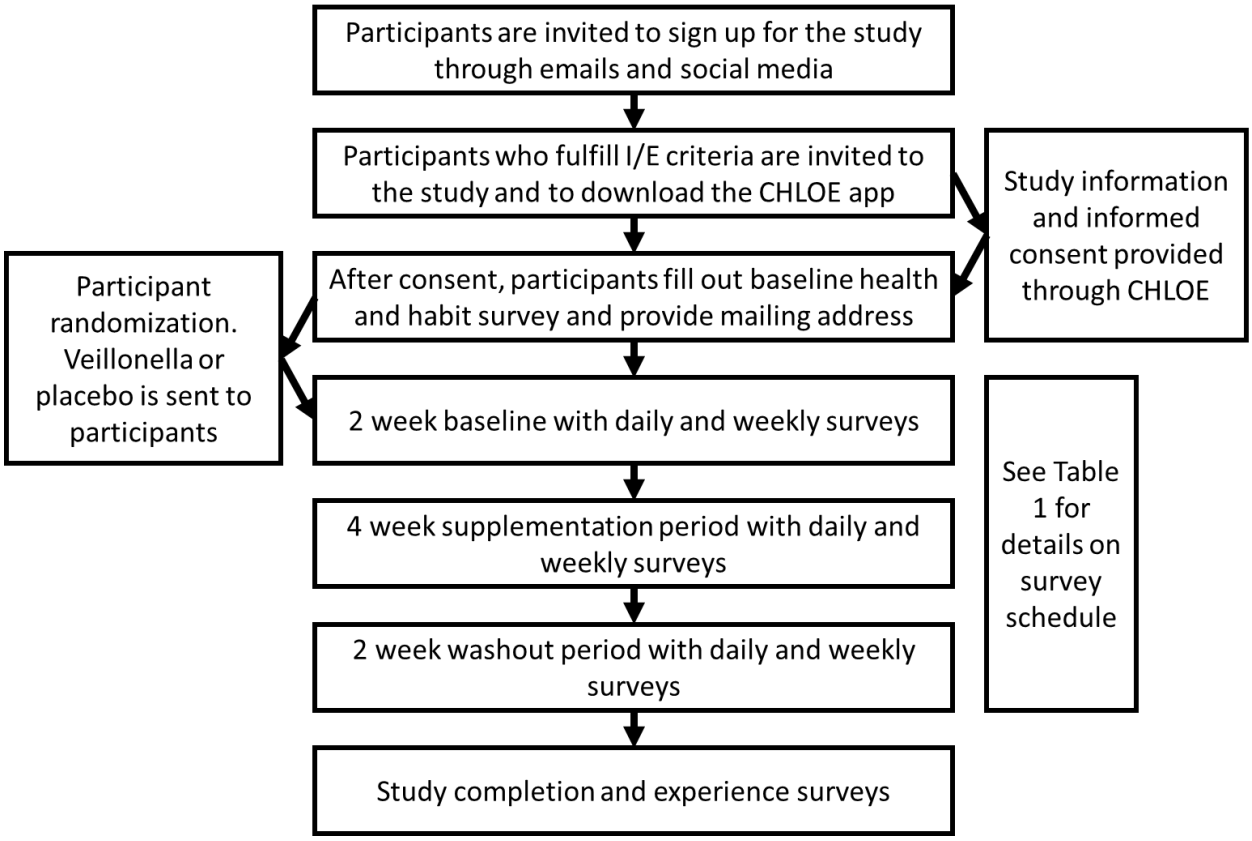

Table 1. Survey Details

Survey Name	Survey Details	Number of Questions	Estimated Time to complete	Number of Times Used	Total survey time
Study sign up form	Form used to express interest in the study, includes questions on participant demographics and to include / exclude participants	18	5 minutes	1X	5 minutes
Baseline survey	Includes questions on daily habits and lifestyle as well as baseline questions on normal fatigue and energy levels	31	10 minutes	1X	10 minutes
Daily survey	Daily assessment of the participant's sleep, energy, and bowel movements	4	< 1 minute	56X	56 minutes
Weekly Survey	Participants are asked to look back at their week and report their feelings of fatigue, energy, mood, and health, as well as their exercise and other physical activity	18	5 minutes	8X	40 minutes

MFI	A self-report instrument designed to measure fatigue. It covers the following dimensions: General Fatigue, Physical Fatigue, Mental Fatigue, Reduced Motivation and Reduced Activity.	20	5 minutes	2X	10 minutes
GSE	PROMIS self-efficacy survey designed to be non-disease specific measure of life management and physical functioning	4	< 1 minute	2	2 minutes
End of study survey	A repetition of some questions from the baseline survey to assess whether there have been significant changes over the course of the study	4	< 1 minute	1	1 minute
Experience survey	Mostly open ended questions on experience in the study itself, including questions designed to inform future marketing of Veillonella	6	5 minutes	1	5 minutes
				Total survey time	139 minutes

Table 2. Survey Schedule

	Recruitment	**Pre-Week 1**	**Week 1**	**Week 2**	**Week 3**	**Week 4**	**Week 5**	**Week 6**	**Week 7**	**Week 8**
Study sign up form	1X									
Informed consent		1X								
Baseline survey		1X								
Daily survey			Daily (7X)	Daily (7X)	Daily (7X)	Daily (7X)	Daily (7X)	Daily (7X)	Daily (7X)	Daily (7X)
Weekly survey			1X at end of week	1X at end of week	1X at end of week	1X at end of week	1X at end of week	1X at end of week	1X at end of week	1X at end of week
MFI				1X at end of week				1X at end of week		
GSE				1X at end of week				1X at end of week		
End of study survey										1X at end of week

Experience survey										1X at end of week

Completing Research Activities

Compensation

Participants will receive points in the Chloe mobile app to be used toward an Amazon Gift Card and be provided with a discount code to purchase the Nella probiotic.

Research results or clinical findings arising from research activities

Due to the nature of the study, it is unlikely that research results or findings from research activities will result in further medical-related expenses for the participant.

Risk/Safety Information

Starting a new probiotic tends to result in mild and transient gastrointestinal upset. In our previous pilot human studies, we have observed these symptoms, but they were mild enough to not interfere with a run-to-exhaustion endpoint. The surveys used in this study include a question on potential symptoms experienced, which will allow us to identify additional potential AEs as well as known side effects that persist longer than expected.

For Veillonella:

Very common (greater than or equal to 1/10)

- Mild gastrointestinal upset including temporary increases in gas, bloating, cramping, and nausea
- Nervousness and increased feelings of anxiety

For Placebo:

- None known

Other risks of study procedures

Questionnaires: The questions used in this survey may cause temporary discomfort or distress to the participant. The survey is designed to be simple and short and is a commonly used tool in clinical studies. The participant may choose not to complete the questionnaire.

Breach of Confidentiality: There is minimal risk that people who are not connected with this study will learn of the participant's identity or personal information. The study staff will be GCP trained and will utilize best practices when using the data platform to ensure participant privacy protections.

Unforeseen Risks

There may be other risks that are unknown. Additionally, there may be unknown risks to a pregnancy, embryo, or fetus if you or your female partner become pregnant.

Risk Level Determination

The risks to the study are minimal or unanticipated due to appropriate mitigation measures (e.g. breach of confidentiality, loss of internet access). This research meets the federally defined definition of minimal risk (45CFR 46.102(j)).

Alternatives to Participation

The individual can choose not to participate.

Participant Withdrawal from Research/ Research Activities

Research activities are limited to five weeks.

Participants may withdraw from the study at any time and for any reason without prejudice. The withdrawal must be documented.

Monitoring/Reporting of AE/SAE

AEs and SAEs will be detected using the weekly surveys. On a weekly basis, participants are asked if they have stopped taking the product due to side effects. If they answer in the affirmative, they can provide more information on the symptoms and their severity. Participants can also report AEs and SAEs to the study staff at any time via phone or email.

An AE is defined as any reported side effect of the product that is likely due to Veillonella itself. Based on our previous work, we anticipate mild and transient gastrointestinal upset as well as mild anxiety as possible common AEs.

An SAE is defined as any severe and/or unexpected side effect that is life threatening, requires medical or surgical intervention, or is otherwise an important medical event for the patient. SAEs are also AEs that result in hospitalization, disability or permanent damage, or death. These will be reported to the FDA.

FitBiomics is utilizing a company called SafetyCall for AE monitoring and reporting in this study. SafetyCall will provide adverse event management, incident documentation, and first aid advice for basic on-site patient management, general medical and clinical toxicology consultation for health care providers, and health and safety information to the study participants, customers, medical personnel, and others. Services are provided by telephone 24 hours a day, 365 days a year.

SafetyCall will also provide adverse event management and incident documentation for non-telephone based correspondence such as consumer email, customer service notifications, internet-based inquiries and written communications. These services include an initial professional assessment for health risk and triage. SafetyCall will respond to any inquiries it receives, including incidents involving either humans or animals consistent with standard of care practices. A lead toxicologist is available from 9:00am to 5:00pm Central Standard Time, Monday through Friday. An on-call toxicologist is available after hours.

SafetyCall will also manage reporting of AEs to the FDA. In compliance with the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Pub. L. 109-462, 120 Stat. 3469), any correspondence or verbal notification of a potential adverse event (AE) in association with a dietary supplement received by a manufacturer and/or its subsidiaries will be documented according to FDA mandated data collection guidelines and all records retained for a minimum of 6 years for potential review by the FDA. Those

adverse events meeting the FDA defined criteria for serious will be reported to the FDA within 15-business days using the FDA Form 3500A and its accompanying data elements.

Study Oversight

This study will be made available for monitoring, auditing, IRB review and regulatory inspection by providing direct access to study related source data.

Ethical and Regulatory Standard

This study will be conducted in conformance with the principles set forth in The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979) and the Declaration of Helsinki.

This study is to be conducted in compliance with the IRB approved protocol and according to applicable federal, state, local and tribal laws including the following:

- US Code of Federal Regulations (CFR) governing clinical study conduct: Title 45 Part 46 – Protection of Human Subjects
- US Code of Federal Regulations relating to the Health Insurance Portability and Accountability Act of 1996: Title 45 Part 164 – Security and Privacy – Subpart E - ○ Subpart E—Privacy of Individually Identifiable Health Information
- State of California Health and Safety Code, Title 17, for research conducted in California

In addition, this study is to be conducted in compliance with applicable policies and procedures of the Advarra IRB, applicable institutional research policies and procedures, applicable institutional clinical policies and procedures, and applicable NIH policies and procedures.

IRB Review / Ethics / Informed Consent

The protocol, informed consent form(s), recruitment materials and all participant materials will be submitted to the Advarra IRB for review and approval. Approval of both the protocol and the consent form must be obtained before any participant is enrolled. Any amendments to the protocol or consent materials will require review and approval by the IRB before the changes are implemented in the study.

Per the federal regulations at 45 CFR 46 and State of California Health and Safety code, Title 17, must review and approve this protocol and the informed consent process and its documents prior to initiation of the study. All institutional, NIH, Federal, and State of California regulations must be fulfilled.

Any documents that the IRB may need to fulfill its responsibilities (such as protocol, protocol amendments, consent forms, information concerning participant recruitment, payment or compensation procedures, or other pertinent information) will be submitted to the IRB. The IRB's written approval of the study protocol and the informed consent document will be in the possession of the investigator before the study is initiated.

Any amendment to the protocol document and accompanying informed consent documents, as developed and provided by the PI, will require review and approval by the IRB of record before the changes are implemented in the study.

Study Compliance and Reporting Deviations

A deviation is a divergence from a specific element of a protocol and that occurred without prior IRB approval. Deviations from the approved protocol will be avoided, except when necessary to eliminate an immediate hazard to a research participant. All deviations from the protocol will be documented in study source documents and promptly reported to the IRB.

Investigators may deviate from the protocol to eliminate immediate hazards for the protection, safety, and well-being of the study subjects without prior IRB approval. For any such deviation, the PI will notify the IRB, within 5 calendar days of its occurrence by electronic submission of a deviation notice.

Conditions for Study Termination or Suspension

This study will be terminated prematurely in the following situations:

- There are unforeseen safety issues or if other studies are published that indicate a presence of unanticipated toxicity risks that cannot be adequately quantified.
- The protocol is determined to no longer meet study or sponsor objectives.

The study PI or the IRB may terminate or suspend this study at any time. If the study is prematurely terminated or suspended, participants will be instructed as to whether they should complete supplementation. Participants will be monitored and continue follow up for 2 weeks after they stop supplementation to ensure their safety and to collect any final data. All participants who have completed at least 50% of surveys at the time that the study is terminated or suspended will be provided with a discount code to purchase the Nella probiotic as compensation.

Informed Consent

Informed consent is a process that is initiated prior to the individual agreeing to participate in the study and continues throughout study participation. Operational details specific to the consenting process that occurs prior to any research evaluations/interventions are described in Section 6.0.

All participants will undergo virtual electronic informed consent after they are determined to qualify for the study. An electronic informed consent document will describe the nature, duration, purpose of the study, potential risks, alternatives and potential benefits, and all other IRB approved information. In addition, the experimental participant's bill of rights and the HIPAA research authorization form will be provided. Prospective research participants will be informed that they may withdraw from the study at any time and for any reason without prejudice. Prospective research participants will be afforded sufficient time to consider whether to participate in the research.

Virtual informed consent will be conducted through the app-based consent form at the participant's convenience. After reading the consent, participants will be able to contact study staff about any study related questions. Once the prospective participant expresses full understanding, virtual informed consent will be obtained through electronic signature from either the prospective participant before study participation. The method of obtaining and documenting the informed consent and the contents of the consent must comply with the ICH-GCP and all applicable regulatory requirements. A copy of the signed consent document will be available to the participant within the Chloe app. The signed consent must be maintained by the investigator and available for inspection by sponsor designated representatives, or regulatory authority at any time.

Privacy Authorization

The informed consent process will include a privacy authorization compliant with 45CFR164.508(c) via the inclusion/incorporation of:

- all core elements specified in 508(c)(1) including the signature of the individual (or representative) and date of signature,
- all required statements specified in 508(c)(2)
- the plain language requirement as specified in 508(c)(3), and
- the provision to the participant (or representative) a copy of the signed authorization (508(c)(4)

State of California Human Experimentation Requirements

This research involves the collection of information via validated questionnaires and obtaining information from the medical record. Research activities do not encompass those that are requisite for a participant to be involved in a "medical experiment" as defined by California State Law 24174. The 'California Experimental Subject's Bill of Rights' will be administered as part of the informed consent process; as part of that process participants will receive a copy of the 'Bill of Rights' marked with their signature.

Data Management

Study data will be stored in secure password-protected servers. Study staff will de-identify all data prior to data analysis. Data will be analyzed to compare the safety and efficacy of Veillonella vs placebo and between the two different doses of Veillonella. We will also use these data to better understand the type of benefits different subsets of participants tend to experience as well as the magnitude of the benefit in these subpopulations. These results will be used to create peer-reviewed publications, academic and industry presentations, file patents, and potentially develop new innovative microbiome products like probiotics. Participants will not be notified of any of these uses.

Confidentiality

All documents and electronic data will be stored on secure, password-protected computers. Participant confidentiality will be strictly held in trust by the investigators, study personnel, and sponsor. No identifiers will be used in any subsequent publication of these results.

Records of participation in this study will be held confidential except when sharing the information is required by law or as described in this informed consent. The Investigator, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the US FDA and the IRB will be able to inspect and copy confidential study-related records and identify subjects by name. This means that absolute confidentiality cannot be guaranteed. This does not limit the duty of the researchers and others to protect participants' privacy. Study records including confidential information about study subjects collected during the study will be kept at a secure location or server. If the results of this study are published or presented at meetings, participants will not be identified.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify participants. At most, the Web site will include a summary of the results.

Return or Clinical Use of Research Results

Participants will be shown their study data in real time as they go through the data visualization modules in the Chloe platform.

Research results will be shared with participants at completion of data analysis. The results of this research may help the participant make decisions in future product purchases and participate in future research studies.

There are no anticipated burdens or financial obligations to research subjects.

Intended Use of the Data

Information/Data Retention, Future Use, and Sharing

The data collected as part of this study will be used to assess the safety and efficacy of Veillonella in this population. These data may be used in peer-reviewed manuscripts, research presentations, and other materials to promote FitBiomics and its platform, or to develop new products. All data will be deidentified prior to any publication or presentation. Prior to the completion of this research, information will be coded, destroyed, de-identified, or provided to a privacy officer.

Publication

The publication or presentation of any study results shall comply with all applicable privacy laws, including, but not limited to, the Health Insurance Portability and Accountability Act of 1996. Neither the complete nor any part of the results of the study carried out under this protocol, nor any of the information provided by the sponsor for the purposes of performing the study, will be published or passed on to any third party without the written approval of the Study PI. Any investigator involved with this study is obligated to provide the sponsor with all data derived from the study.

Biostatistical Analysis Plan

Data Source

The source of the data is the results of the questionnaires filled out through the Chloe app as well as the optional fitness tracker data collected over the course of the study.

Analysis Objectives

The goals of this analysis are to identify whether there are statistically significant differences in effects between the placebo and Veillonella groups as well as between the high and low dose Veillonella groups. Furthermore, for any differences that are observed, we would like to understand whether there are any demographic or other participant characteristics that may be associated with benefits or side effects experienced by the participants.

Analysis Sets / Populations / Subgroups

The three groups compared in this study are high dose Veillonella, low dose Veillonella, and placebo.

In addition, we plan to separately analyze results by gender, age, baseline exercise habits, health history, previous probiotic experience, sleep habits, and other lifestyle factors.

For those participants who share fitness tracker data, the fitness tracker data shared through the Chloe app will be analyzed in conjunction with survey data separately from those who did not share fitness tracker data.

Endpoints

The primary endpoints analyzed in this study are:

- Change in reported physical fatigue
- Change in mental / emotional fatigue
- Change in MFI

The secondary endpoints analyzed in this study are:

- Change in reported sleep quality
- Change in frequency of reported physical activity
- Change in intensity of reported physical activity
- Change in reported exercise
- Change in recovery time
- Change in energy level

The exploratory endpoints analyzed in this study are:

- Changes in fitness tracker data
- Change in reported bowel movements
- Change in GSE
- Change in reported mood
- Change in reported digestive health
- Change in reported general health
- Change in BMI, weight, or waist circumference

Handling of Missing Values

There will likely be missing values related to incomplete or missing surveys. Participants will only be included in the analysis if they completed at least 50% of weekly surveys during each time period: baseline, supplementation, and washout. Values will be binned longitudinally such that each participant included in the analysis has a data point associated with each bin. If there are multiple values associated with a participant in a bin, the mean of those values will be used for the analysis.

Statistical Procedures

The majority of primary and secondary endpoints for this study are questions on the survey which consist of rating scales (generally 1-5 or 1-9). Significant differences between groups for these endpoints will be assessed using an independent T test or Mann-Whitney U test depending on the observed

distribution of the data. For significant changes over time within the same group, a dependent T test will be used.

For differences between groups in terms of primary and secondary endpoints that measure a change in time (e.g. time to recovery in days or hours of sleep), an independent T test or Mann-Whitney U test will be used, depending on the observed distribution of the data. For significant changes over time within the same group, a dependent T test will be used.

To identify demographics associated with any particular response (benefit or side effects), we will use the demographic, health history, and lifestyle information collected in the surveys to build an unsupervised machine learning algorithm (e.g. Random Forest Classifier). If we can build one that effectively classifies the response (AUC > 0.7), we will identify the model's most important features. To confirm that these features are significantly associated with response, we will use an independent T test to assess significant differences between response and non-response.

For all other exploratory endpoints including the optional fitness tracker data, the data type and distribution of that data will determine the statistical analysis used.

Measures to Adjust for Confounders

For all data and endpoints, data can be normalized to the baseline collected values, and change in value at different time points can be compared using the statistical tests described above.

In addition, there is a question included in the weekly surveys assessing how participants are generally feeling about their life, which they respond to using a rating scale from 1 (pessimistic) to 9 (optimistic). If necessary, we can normalize the weekly survey data using this rating to confirm that participant life and stress outside the study are not affecting how they respond to the surveys.

QC Plans

All analyses will be performed by a study bioinformatician or data scientist. All code used for the analysis will be saved using version control software such as Git in the format or Python notebooks. These notebooks will be reviewed by other study staff for errors and certified that analyses are correct prior to any written or oral reports, presentations, or publications on the results of the study.

Programming Plans

All code for these analyses will be written using Python 3 in Jupyter notebooks. The pandas library will be used for importing the data, manipulating it in a data frame, and exporting it as excel or comma-separated files. The Numpy and Scipy libraries will be used for all statistical analysis and the Sci-Kit Learn library will be used for machine learning analyses. Matplotlib and Seaborn libraries will be used for visualization of the data as graphs and charts.

Investigator Conflict of Interest

Investigators will disclose any conflict of interest.

Any investigator who has a conflict of interest with this study (patent ownership, royalties, or financial gain greater than the minimum allowable by their institution, etc.) must have the conflict reviewed by a properly constituted Conflict of Interest Committee with a Committee-sanctioned conflict management

plan that has been reviewed and approved by the study Sponsor prior to participation in this study. All investigators will follow the conflict of interest policy.

References

1. Scheiman J, Luber JM, Chavkin TA, MacDonald T, Tung A, Pham L-D, et al. Meta'omic analysis of elite athletes identifies a performance-enhancing microbe that functions via lactate metabolism. Nat Med. 2019;25:1104–9.

2. Ng SK, Hamilton IR. Carbon dioxide fixation by Veillonella parvula M 4 and its relation to propionic acid formation. Can J Microbiol. 1973;19:715–23.

3. Gross K, Santiago M, Krieger JM, Hagele AM, Zielinska K, Scheiman J, et al. Acute Impact of Veillonella atypica FB0054 Supplementation on Exercise Performance and Lactate Changes: A Randomized, Crossover Pilot. Nutrients. In Review.

4. Preece KE, Glávits R, Murbach TS, Endres JR, Hirka G, Vértesi A, et al. Safety evaluation of Veillonella atypica FB0054 with genotoxicity and subchronic toxicological studies. J Appl Toxicol JAT. 2023;43:808–27.